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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/423,351	05/10/2000	KEITH WILLISON	MEWBURN	6633

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EXAMINER	
CANELLA, KAREN A	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 07/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/423,351	WILLISON ET AL.	
	Examiner	Art Unit	
	Karen A Canella	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) *20-30, 38-43* is/are withdrawn from consideration.

5)☐ Claim(s) *1-17 and 19* is/are allowed.

6)☐ Claim(s) *18 and 31-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-43 are pending. Claims 20-30 and 38-43, drawn to non-elected inventions, remain withdrawn from consideration. Claims 1-19 and 31-37 are under consideration.

The text of sections of Title 35, US code not found in this action can be found in a previous action.

Claims 18 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear how claim 18 further limits claim 11 because claim 18 fails to relate the improvement in binding with the CCT apical domain to the method objective of identifying a binding member as recited in claim 11.

Claim 32 is vague and indefinite in the recitation of "normal biological activity of CCT in a cell" without a definition of normal biological activity of CCT in a cell which would define the metes and bounds of "normal biological activity".

The metes and bounds of the term "modifying" as recited in claim 18 are unclear.

Claims 18 and 31-37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of screening for modified binding members and mimetics which inhibit the binding of actin to the CCT complex, does not reasonably provide enablement for methods of screening for modified binding members and mimetics which inhibit the binding of non-actin substrates to the CCT complex. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims..

Claim 18 embodies the method of claim 11 and further comprises a method step wherein the candidate binding member is modified to improve binding with the CCT apical domain. Claims 31-37 are drawn to methods for identifying mimetic of the binding members capable of occupying a CCT substrate binding site comprising an amino acid sequence of 5-40 amino acids derived from a CCT substrate, wherein said binding member has been identified by the methods

of claims 1 or 11. The specification teaches binding members derived from the CCT substrate of actin as SEQ ID NO:1-15 and 121, wherein said binding members inhibit the binding of actin to the CCT complex. The specification do not teach binding members derived from the CCT substrate of tubulin or cyclins which inhibit the binding of tubulin or cyclin to the CCT complex. In order to carry out the claimed methods including claim 18, it would be necessary to be able to make the binding members to be able to identify compounds which are mimetics of said binding members. However, the instant specification does not teach how to make said binding members other than the BEP epitopes derived from actin (page 47, line 6 to page 52, line 27). The examiner notes that teaching how to identify binding members by means of the disclosed assay on CCT, is not equivalent to teaching how to make the binding members. Thus, one of skill in the art would be subject to undue experimentation in order to carry out the broadly claimed methods because one of skill in the art would first be required to identify the binding members and subsequently further identify the mimetics.

Claims 18 and 31-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. .

Claims 18 and 31-37 are reliant upon the identity of the binding members identified in claims 1 and 11. The specification teaches how to identify binding members that inhibit the binding of the CCT complex to the CCT substrate, wherein the binding members are derived from the CCT substrates of actin, tubulin and cyclins. The specification does not provide a written description of "modified" the binding members which would improve the binding of the binding member to the CCT complex. The specification does not provide a written description of "mimetics" of the binding members derived from actin (SEQ ID NO:1-15). The specification does not provide any specific examples of binding members derived from CCT substrates other than actin, so it necessarily follows that the specification does not provide an example of a mimetic of said binding members, or a modification of said binding members.

Although drawn to DNA arts, the findings in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) and Enzo Biochem, Inc. V. Gen-Probe Inc. are relevant to the instant claims. The Federal Circuit addressed the application of the written description requirement to DNA-related inventions in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The court stated that "[a] written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." Id. At 1567, 43 USPQ2d at 1405. The court also stated that

a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA" without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. Id. At 1568, 43 USPQ2d at 1406. The court concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id.

Finally, the court addressed the manner by which a genus of cDNAs might be described. "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." Id.

The Federal Circuit has recently clarified that a DNA molecule can be adequately described without disclosing its complete structure. See Enzo Biochem, Inc. V. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The Enzo court adopted the standard that "the written description requirement can be met by 'show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ....i.e., complete or partial

structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. " Id. At 1324, 63 USPQ2d at 1613 (emphasis omitted, bracketed material in original).

The inventions at issue in Lilly and Enzo were DNA constructs per se, but the holdings of those cases are also applicable to claims such as those at issue here. A disclosure that does not adequately describe a product itself logically cannot adequately describe a method of using that product.

Thus, the instant specification may provide an adequate written description of the binding members, per Lilly by structurally describing a representative number of binding members or by describing "structural features common to the members of the genus, which features constitute a substantial portion of the genus." Alternatively, per Enzo, the specification can show that the claimed invention is complete "by disclosure of sufficiently detailed, relevant identifying characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics."

In this case, the specification does not describe the binding members required to practice the methods of claims 18 and 31-37 in a manner that satisfies either the Lilly or Enzo standards. The specification provides only the binding members derived from the CCT substrate actin and does not describe binding members derived from any other CCT substrate such as tubulin and cyclins. The specification does not provide any partial structure of said binding members derived from non-actin CCT substrates, nor any physical or chemical characteristics of the binding members derived from non-actin CCT substrates, nor any known or disclosed correlation between structure and function, such as a binding motif present in the CCT substrates wherein peptides comprising said binding motif would function to inhibit the binding of the CCT substrate to the CCT complex. Although the specification discloses a representative genus of binding members derived from actin, this does not provide a description of binding members derived from non-CCT substrates that would satisfy the standard set out in Enzo.

The specification also fails to describe the binding members by the test set out in Lilly. The specification describes only binding members derived from the single CCT substrate of actin. Therefore, it necessarily fails to describe a "representative number" of such species

because the species disclose represent only those derived from a single CCT substrate. In addition, the specification also does not describe "structural features common to the members of the genus, which features constitute a substantial portion of the genus", with respect to the non-actin CCT substrates.

Thus, the specification does not provide an adequate written description of the binding members capable of inhibiting the binding of the CCT substrate to the CCT complex.. Since the specification fails to adequately describe the product on which the claimed methods rely, it also fails to adequately describe the claimed methods.

Applicant argues that possession may show in may ways including reduction to practice . It is noted that applicant has only reduced to practice the method wherein the binding members are derived from the CCT substrate of actin. Applicant further argues that in the Trilateral Report on the Questionnaire for Comparative Study on "Reach Through Claims", assays for identifying agonist compounds are found to be patentable in principle even if no working examples are carried out, providing the steps of the method are adequately described. Applicant contends that the rejection applied to a method of screening for products is improper. This has all been considered but not found persuasive. Method claims relying on products which have not yet been described, such as those at issue in claims 18 and 31-37, cannot themselves be described. The steps of the instant method rely upon the identity of the binding members of identified by claims 1 and 11. This is not a similar fact pattern to the example referred to in the Trilateral Report wherein the claims drawn to the screening of agonists where reliant upon the identity of a fully characterized receptor.

All other rejections and objections as set forth in the previous Office action are withdrawn in light of applicants amendments and arguments.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10 a.m. to 9 p.m. M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571)272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Canella, Ph.D.
6/14/2004

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PRIMARY EXAMINER